

Serial No. 09/096,247

Office Action mailed on April 6, 1999. Please cancel all claims and enter the following new claims.

17. A solution formulation comprising: a physiologically tolerated buffer selected from the group consisting of TRIS and arginine; a monomeric insulin analog wherein the insulin analog is Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin; zinc; and a phenolic preservative.
18. The formulation of Claim 17, wherein the buffer is TRIS.
19. The formulation of Claim 18 further comprising an isotonicity agent and wherein the pH of the formulation is between pH 7.0 and pH 8.0 when measured at a temperature of 22°C.
20. The formulation of Claim 19, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 1.2 mg/mL and about 50 mg/mL.
21. The formulation of Claim 20, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 3.0 mg/mL and about 35 mg/mL.
22. The formulation of Claim 21, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 3.5 mg/mL and about 35 mg/mL.
23. The formulation of Claim 22, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 7 mg/mL and about 35 mg/mL.
24. The formulation of Claim 23, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 14 mg/mL and about 35 mg/mL.

- <sup>9</sup>  
~~25~~. The formulation of Claim <sup>8</sup>~~24~~, wherein the concentration of Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin is between about 17.5 mg/mL and about 35 mg/mL.
- <sup>10</sup>  
~~26~~. The formulation of Claim <sup>6</sup>~~22~~, wherein the phenolic preservative is a mixture of m-cresol and phenol.
- <sup>11</sup>  
~~27~~. The formulation of Claim <sup>10</sup>~~26~~, wherein TRIS is present at a concentration of about 2 mg/mL; glycerol is the isotonicity agent and is present at a concentration of about 16 mg/mL; and wherein m-cresol is present at a concentration of about 1.76 mg/mL and phenol is present at a concentration of about 0.715 mg/mL.
- <sup>12</sup>  
~~28~~. A stable, soluble formulation of a monomeric insulin analog, for use in a continuous infusion system, consisting essentially of: an isotonicity agent; a buffer selected from the group consisting of TRIS and arginine; Lys<sup>B28</sup>Pro<sup>B29</sup>-human insulin; zinc; and a phenolic preservative.
- <sup>13</sup>  
~~29~~. The ~~monomeric insulin analog~~ formulation of Claim <sup>1</sup>~~28~~, which further comprises protamine.
- <sup>14</sup>  
~~30~~. A method for treating diabetes comprising administering an effective dose of the formulation of Claim <sup>1</sup>~~29~~ to a patient in need thereof.
- <sup>15</sup>  
~~31~~. The method of Claim <sup>14</sup>~~30~~, wherein the formulation is administered using a continuous infusion system.
- <sup>16</sup>  
~~32~~. A method for treating <sup>hyperglycemia</sup>~~hypoglycemia~~ comprising administering an effective dose of the formulation of Claim <sup>1</sup>~~31~~ to a patient in need thereof.